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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,688	04/03/2002	Klaus Ducker	MERCK 2402	5557

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EXAMINER	
MONDESI, ROBERT B	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,688	DUCKER ET AL.	
	Examiner	Art Unit	
	Robert B Mondesi	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *4-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date Sep 11 2002
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to restriction requirement

Applicant's election with traverse of Invention I, **Claims 1-3** in amendment, filed October 12, 2004 is acknowledged. The traversal is on the ground(s) that the search of claims in the application would comprise overlapping subject matter and it would not be an undo burden on the examiner to search all the claims. This is not found persuasive because the search of the products of the invention involves the use of completely unrelated databases. For example the databases used to search the polypeptide of the invention are not the same as the data bases to search the polynucleotide of the invention. Since there is no possibility of a simultaneous search the removal of the restriction requirement would impose a burden on the examiner and the United States Patent office. Furthermore the product as claimed is not allowable therefore method claims drawn to a process of using or a process of making can not be rejoined

Therefore the requirement is still deemed proper and is made FINAL. **Claims 1-11** are pending in this application. The examiner would like to clarify that claim 4 is drawn to a polynucleotide and therefore belongs in Group II. **Claims 4-8 and 10-11** are withdrawn. **Claims 1-3 and 9** are currently under examination, **claim 9** has been rejoined because it is drawn to a fusion protein and can be searched without imposing a burden on the examiner.

Priority

The current application filed on April 03, 2002 is a 371 of PCT/EP00/09475 filed on September 28, 2000, which in turn claims priority to foreign application, (EPO) 99119113.1 filed on October 04, 1999.

Preliminary Amendment

The preliminary amendment filed April 03, 2002 has been entered.

Information Disclosure Statement

The IDS filed April 03, 2002 has been received and is signed and considered, a copy of the PTO 1449 is attached to the following document.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to functional derivatives/natural variant of the polypeptide comprising the amino acid sequence designated as SEQ ID NO: 2. The claims do not

require that the polypeptide possess any particular conserved structure, or other distinguishing feature, such as a specific biological activity. Thus, the claims are drawn to a genus of polypeptides that is defined by an unclear functional relationship to the polypeptide comprising the amino acid sequence designated as SEQ ID NO: 2. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, and any combination thereof. In this case, the only factor present in the claim that is sufficiently disclosed is a partial structure in the form of a recitation of percent identity. The specification does not identify any particular portion of the structure that must be characteristics of the claimed genus are not described. The only adequately described species is the polypeptide comprising the amino acid sequence designated as SEQ ID NO: 2 and no active variants are disclosed. Accordingly, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states, "applicant must convey with reasonable clarity to those skilled in the a14 that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed." (See page 1117.) The specification does not it clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116), As discussed above, the

skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers* v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. One cannot describe what one has not conceived. See *Fiddes v. Baird,* 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF' s were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Therefore, only the polypeptide comprising the amino acid sequence designated as SEQ ID NO: 2, but not the full breadth of the claim meets the written description provision of 35 U. S.C. 112, first paragraph. Applicant is reminded that *Vas-cath* makes clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision

Claims 1-3 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In **claim 1** the language, "selected from one of the groups consisting of" is indefinite. There can be only one group from which to select. **Claims 2-3 and 9** are dependent claims that do not further clarify the independent claim that they depend from.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3 and 9 are rejected under U.S.C 101 because the claimed invention is not supported by either specific and substantial asserted utility or well established utility.

Claims 1-3 and 9 are directed to an isolated protein comprising the amino acid sequence of SEQ ID NO: 2. The instant specification discloses that the polypeptide comprising the amino acid sequence presented in SEQ ID NO: 2 is a protein that belongs to the family of newly discovered proteins, the human Acute Neural Induced Calcium-Binding Proteins (ANIC-BP) and that the protein of the invention has structural similarity with the mentioned human Acute Neural Induced Calcium-Binding Proteins (ANIC-BP).

Pages 15-22 of the instant application describes the uses and methods of the invention, and state that the protein of the invention can be used in methods such as detecting assay, production of antibodies, northern blotting, determination of levels of production of polypeptides, production of vaccines and methods of treatment and that the protein of the invention has structural similarity with human Acute Neural Induced Calcium-Binding Proteins (ANIC-BP). The specification further asserts that the protein of the invention can be used for screening for drugs (or high throughput screening of combinatorial libraries) effective in the treatment of the symptomatic or phenotypic

manifestations of perturbing the normal function of human Acute Neural Induced Calcium-Binding Proteins (ANIC-BP) in the body and can be used directly to treat disease and disorders.

However these are not considered to be specific or substantial utilities for proteins. The methods such as recombinant production of protein, detecting assays, production of antibodies, northern blotting, determination of levels of production of polypeptides are considered to be general methods, and are not considered to be specific and substantial utilities.

It is asserted in the specification that the polypeptide of the invention has structural similarity with human Acute Neural Induced Calcium-Binding Proteins (ANIC-BP). However the applicants have not shown any evidence that the polypeptide of the invention has primary structural similarity with human Acute Neural Induced Calcium-Binding Proteins (ANIC-BP) or that there is a disease or disorder correlated with the protein of the invention. The use of unknown amino acids to determine structural similarity with other amino acid sequences by itself does not constitute a specific and substantial utility. Based on assumed structural similarity alone, the specification asserts that protein of the invention is related to the family of human Acute Neural Induced Calcium-Binding Proteins (ANIC-BP). However, The applicant is reminded that function prediction from structure or structure prediction from function is not a reliable measure of utility. Novel human proteins of the invention are assumed to have structural similarity to human Acute Neural Induced Calcium-Binding Proteins (ANIC-BP) but since the function of the protein of the invention is not known it would not be conclusive to

assume, solely based on structure homology, that they have the same function and would have the same utility. It is necessary to carry out further characterization of this protein to assess the patentable utility of the protein.

In Brenner v. Manson, 148 U.SP.Q 689 (Sus. Ct,.1966), a process of producing a novel compound that was structurally analogous to other compounds which were known to posses anticancer activity was alleged to be useful because the compound produced thereby was potentially useful as anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The instant claims are drawn to a novel human protein which has undetermined function or biological significance. Thus no actual or specific activity is attributed to the protein identified in the specification as a novel protein related to the family of human Acute Neural Induced Calcium-Binding Proteins (ANIC-BP).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 9 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and

substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Even if the specification were enabling of how to use the protein of the invention, enablement would not be found to be commensurate in scope with the claims. As discussed in ***USC 101 and 112*** rejections above, the specification has not taught the skilled artisan how to use the polypeptide of SEQ ID NO: 2 that is disclosed in the instant specification. Since the applicants have not characterized the polypeptide of the invention with regards to function and activity a person skill in art would not be able to know how to use the claimed invention.

Prior Art

The examiner note that the protein having SEQ ID No:2 is not taught by the prior art.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RR
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11-12-04

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